



Solutions for Daily Living

Section 7-1

K130644

510(k) Summary-B

Columbia Medical's Pediatric Folding Wheelchair

8/30/2013

1) General Information

Submitter Name: Columbia Medical, LLC
Address: 11724 Willake St.
Santa Fe Springs, CA 90670
Telephone: (562) 282-0244
Fax: (310) 305-1718
Contact Person: Gary Werschmidt
Registration Number: 3005328749

OCT 16 2013

2) Device

Device Trade Name: Pediatric Folding Wheelchair
Common/Generic Name: Pediatric Wheelchair
Device Classification Name: Mechanical Wheelchair
Registration Number: 3005328749
Product Code: LBE
Device Classification: Class 1
Regulatory Number: 890.3850
K Number: K130644

3) Identification of Legally Marketed Predicated Devices

Manufacturer Name: Convoid Products, Inc.
Name: Cruiser CP4M
K Number: K810676
Date Cleared: 03/26/1981

4) Description of the device:

This pediatric wheelchair, also commonly referred to as an adaptive stroller, is constructed of the same typical components of most manual wheelchairs. The frame consists of powder coated round tubular 6061 T6 aluminum which is 1" in diameter, and is welded and bolted. The device comes standard with 13.5" rear wheels and 6" steering front casters. The back and seating area is made of a fabric material. The wheelchair is designed for everyday indoor and outdoor use in firm terrain. The wheelchair is designed to allow for adjustments of the orientation of the seat and back angles, using tools, to provide seating and back angles to support the skeletal and muscular characteristics of the individual for comfort, control and safety during sitting and mobility.



5) Indication For Use:

The Columbia Medical Pediatric Folding Wheelchair is a manual wheelchair designed to provide mobility aid for children and adolescents who have limited or no ability to ambulate and require a device to aid in seated mobility in the home and community.

6) Technological Characteristics and Substantial Equivalence Device Description:

The product consists of an aluminum tubing frame, steel components, rear wheels and smaller front pivoting casters for steering and turning. The product is designed to be lightweight, user adaptable, everyday wheelchair for both indoor and outdoor use. The Convaid Cruiser is made of similar tubing, aluminum and steel components, and is lightweight, user adaptable, and designed for both indoor and outdoor use.

Similar to the Convaid Cruiser, the Columbia Medical Pediatric Folding Wheelchair frame is welded and bolted and secured with fasteners to allow the size of the chair to be modified as needed to accommodate change or growth of the individual. The medical equipment provider can make many of the changes without additional parts.

This wheelchair is designed to be folded for stowage and storage without the use of tools. Although the folding methodology for the Columbia Medical Pediatric Folding Wheelchair and the Convaid Cruiser is dissimilar, the result is a folded frame designed for easier transportability or storage.

7) Non-Clinical Testing

Columbia Medical's Pediatric Folding Wheelchair was evaluated for front, rear and sideway stability tests, dimensional conformance, fatigue, curb drop, and impact tests, which are RESNA standards for the predicate device. Testing was performed to ensure that the Columbia Medical's device was equivalent to the predicate device.

Additionally the base material in the fabric, WeatherMax FR, has flame retardant applications to meet CSFM T19, CPAI-84, FMVSS 302 and AST,-E84 Class A.

8) Previous Submissions for this Device

This device has not previously been submitted for FDA approval.



Solutions for Daily Living

Section 7-3

9) Patient contact with surfaces

The surfaces of the wheelchair which might come in contact with the user are the fabric seat/back and the footrests while the user is seated in the wheelchair (less than 24 hour duration). The fabric seat and back are made of WeatherMax FR, in the family of Cordura, which is the similar fabric used by the predicate device fabric seat and back. The footplates are made of ABS which is similar to the material used for the footplates on the predicate device. Biocompatibility test reports for these materials are provided with this submission indicating materials are non-hazardous.

10) Safety

The Columbia Medical Pediatric Folding Wheelchair is substantially equivalent to the predicated device listed in the 510(k). The construction and the design of this wheelchair do not raise any new issues of safety and effectiveness.

11) Conclusion:

The Pediatric Folding Wheelchair shares similar materials, performance features and construction technology with the predicate device as well as a number of similar devices already legally marketed within the United States.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 16, 2013

Columbia Medical Manufacturing, LLC
c/o Gary Werschmidt,
Chief Executive Officer
11724 Willake St.
Santa Fe Springs, CA 90670

Re: K130644

Trade/Device Name: Pediatric folding wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I
Product Code: LBE
Dated: September 4, 2013
Received: September 6, 2013

Dear Mr. Werschmidt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130644

Device Name: Pediatric Folding Wheelchair

Indications For Use:

The Columbia Medical Pediatric Folding Wheelchair is a manually propelled wheelchair designed to provide mobility aid for children and adolescents who have limited or no ability to ambulate and require a device to aid in seated mobility in the home and community.

Prescription Use ☒
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☒
 (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S